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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,326	06/14/2001	David B. Rozema	Mirus.013.02	1467

7590

02/05/2003

Mark K. Johnson  
PO Box 510644  
New Berlin, WI 53151-0644

EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/05/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**Application No.  
**09/881,326**Applicant(s)  
**Rozema et al.**Examiner  
**William Sandals**Art Unit  
**1636**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 20, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_
- Claim(s) objected to: \_\_\_\_\_
- Claim(s) rejected: 1-3
- Claim(s) withdrawn from consideration: \_\_\_\_\_
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

**REMY YUCEL, PH.D**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



UNITED STATES DEPARTMENT OF COMMERCE

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DEA/FCE-1994

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09/881,326			

EXAMINER	
William Sandals	
ART UNIT	PAPER NUMBER
1636	12

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

Paper No. 11, filed on January 20, 2003 entitled "Supplemental Information" has been entered.

Arguments in Paper No. 11 assert that US Patent No. 5,698,531 (Nabel et al.) does not teach transfection of extravascular parenchymal cells. An excerpt from an article authored by Elizabeth Nabel, published in 1995, has been cited to support this position. The last sentence of the cited excerpt states "Injury to the vessel and/or application of pressure to the vector infusate results in delivery of DNA transmurally and gene expression in the media". An interpretation of this sentence is that the cells beyond the blood vessel are transfected, and that this transfection

Art Unit: 1636


occurs as a result of "application of pressure" to the solution containing the DNA. This being the case, the argument is not found convincing.

Sections from the file history of US Patent No. 5,698,531 at pages 3, 5, 10 and 19 of an amendment filed on November 22, 1993 are cited in evidence of lack of transformation of extravascular parenchymal cells. The cited section at page 3 does not discuss delivery of DNA to extravascular parenchymal cells, and is only a general statement of site-specific transformation of cells (no specific reference to any cell type). The cited section at page 5 is silent on the transfection of extravascular parenchymal cells. The cited section at page 10 does not discuss the transfection of extravascular parenchymal cells. The cited section at page 19 is a discussion of the prior art, and does not address transfection of extravascular parenchymal cells with a solution introduced via a balloon catheter. The cited examiner's interview only touches on issues related to the prior art, and does not discuss the transfection of extravascular parenchymal cells.

Thus, the arguments set forth in the instant Paper No. 11, have not provided evidence to show that Nabel et al. do not teach transfection of extravascular parenchymal cells. Therefore, the rejection of the claims stands as presented in the final office action of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Sandals whose telephone number is (703) 305-1982. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 7:00 PM.

January 30, 2003

  
**REMY YUCEL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**